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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,913

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Michael M. Grunstein

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/645,913	<b>Applicant(s)</b> GRUNSTEIN ET AL.	
	<b>Examiner</b> MICHAEL SZPERKA	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-14 and 17-45 is/are pending in the application.
- 4a) Of the above claim(s) 10,23 and 27-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-9, 11-14, 17-22 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20, 2007 has been entered.

Applicant's response and amendments received November 20, 2007 are acknowledged.

Claims 1, 4-7, 9, 11, 12, 14, 17-20, 22, 24, and 25 have been amended.

Claims 2, 3, 15, and 16 have been canceled.

Claims 1, 4-14, and 17-45 are pending.

Claims 10, 23, and 27-45 stand withdrawn from consideration as being drawn to nonelected inventions. See 37 CFR 1.142(b) and MPEP § 821.03, for reasons of record set forth in the restriction requirement mailed April 17, 2006.

Claims 1, 4-9, 11-14, 17-22 and 24-26 are under examination as they read on methods of inhibiting the induction of an asthmatic state by administering antibodies or antibody fragments that bind FcεRII and inhibit the binding of IgE to FcεRII.

2. The Declaration of inventors Michael Grunstein and Hakon Hakonarson under 37 CFR 1.131 received as part of the response of November 20, 2007 is acknowledged and will be discussed in conjunction with the rejections of record to which its subject matter is addressed.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1, 7-9, 11-14, 20-22, and 24-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in view of applicant's claim amendments received November 20, 2007 which indicate that the active agent administered in the claimed methods is an antibody or antibody fragment that binds FcεRII (i.e. CD23).

5. The rejection of claims 1, 7-9, 11-14, 20-22, and 24-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicant's claim amendments received November 20, 2007 which indicate that the active agent administered in the claimed methods is an antibody or antibody fragment that binds FcεRII (i.e. CD23).

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The rejection of claims 1, 4-9, 12-14, 17-22, 25, and 26 under 35 U.S.C. 102(e) as being anticipated by Reff et al. (US Patent 6,011,138) has been withdrawn since the invention disclosed by Reff et al. is not recited in the claims of the '138 patent.

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8. Claims 1, 4-9, 12-14, 17-22, 25, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Reff et al. (US Patent 7,033,589) as evidenced by Nakamura et al. (International Journal of Immunopharmacology, 2000, 22:131-141).

Reff et al. disclose and claim methods of administering monoclonal anti-FcεRII (anti-CD23) antibodies that inhibit the binding of IgE to CD23 to humans for the treatment of asthma (see entire document, particularly the abstract, column 2, column 38, and claims 1-15). These antibodies are formulated into compositions for administration via a variety of routes, including intravenous and intramuscular (see lines 21-26 of column 40 as well as claims 6, 7, 12, and 13). Physiological saline solutions are taught for use with parenteral administration (see particularly from line 30 of column 43 to line 14 of column 44). The text of issued claims 1, 4, 5 and 11 read as follows:

1. A method of inhibiting production of IgE in a human subject with an IgE-mediated allergic disorder comprising parenterally administering an IgE production inhibiting amount of an anti-human CD23 monoclonal antibody comprising a human gamma-1 constant region; which antibody comprises the complementarity-determining regions CDR1, CDR2, and CDR3 of the light and heavy chains of antibody 6G5 or of antibody 5E8; wherein CDR1, CDR2, and CDR3 of the light chain of antibody 6G5 are the polypeptides encoded by nucleotides 124-165, 211-231, and 328-357, respectively, of SEQ ID NO. 1; CDR1, CDR2, and CDR3 of the heavy chain of antibody 6G5 are the polypeptides encoded by nucleotides 148-165, 208-258, and 355-390, respectively, of SEQ ID NO. 3; CDR1, CDR2, and CDR3 of the light chain of antibody 5E8 are the polypeptides encoded by nucleotides 136-168, 214-234, and 331-357 respectively, of SEQ ID NO. 5; and CDR1, CDR2, and CDR3 of the heavy chain of antibody 5E8 are the polypeptides encoded by nucleotides 148-168, 211-261, and 358-378, respectively, of SEQ ID NO. 7.

4. A method of treating an IgE mediated allergic disorder in a human subject comprising parenterally administering a therapeutically effective amount of an anti-human CD23 monoclonal antibody comprising a human gamma-1 constant region; which antibody comprises the complementarity-

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determining regions CDR1, CDR2, and CDR3 of the light and heavy chains of antibody 6G5 or of antibody 5E8; wherein CDR1, CDR2, and CDR3 of the light chain of antibody 6G5 are the polypeptides encoded by nucleotides 124-165, 211-231, and 328-357, respectively, of SEQ ID NO. 1; CDR1, CDR2, and CDR3 of the heavy chain of antibody 6G5 are the polypeptides encoded by nucleotides 148-165, 208-258, and 355-390, respectively, of SEQ ID NO. 3; CDR1, CDR2, and CDR3 of the light chain of antibody 5E8 are the polypeptides encoded by nucleotides 136-168, 214-234, and 331-357, respectively, of SEQ ID NO. 5; and CDR1, CDR2, and CDR3 of the heavy chain of antibody 5E8 are the polypeptides encoded by nucleotides 148-168, 211-261, and 358-378, respectively, of SEQ ID NO. 7.

5. The method of claim 4, wherein said allergic disorder is selected from the group consisting of allergic rhinitis, allergic contact dermatitis, anaphylactic reactions, asthma, and bronchitis.

11. The method of claim 1, wherein said allergic disorder is selected from the group consisting of allergic rhinitis, allergic contact dermatitis, anaphylactic reactions, asthma, and bronchitis.

Note that the "asthmatic state" is a characteristic of asthma patients, and that the same agent (i.e. an anti-CD23/Fc $\epsilon$ RII antibody) was administered to the same patient population as per the instant claims. Also note that 5E8 and 6G5 both block the binding of IgE to Fc $\epsilon$ RII (Nakamura et al., see entire document particularly Figure 1).

Therefore, the prior art anticipates the claimed invention.

It is noted that the response received November 20, 2007 contained a complete declaration under 37 CFR 1.131 by inventors Michael Grunstein and Hakon Hakonarson which attempts to establish invention of the instant claimed invention prior to the earliest claimed priority date of Reff et al. for the purpose of disqualifying Reff et al. as prior art.

This declaration is not persuasive. The Reff et al. reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP Chapter 2300. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The rejection of claims 1, 11, 14, and 24 under 35 U.S.C. 103(a) as being unpatentable over Reff et al. (US Patent 6,011,138) in view of Cockcroft et al. (J. Allergy Clin. Immunol. 1987, 79:734-740) has been withdrawn since the methods disclosed by Reff et al. are not recited in the issued claims.

11. Claims 1, 11, 14, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reff et al. (US Patent 7,033,589) in view of Cockcroft et al. (J. Allergy Clin. Immunol. 1987, 79:734-740, of record).

The disclosure of Reff et al. has been discussed supra. This disclosure differs from the instant claimed invention in that administration of anti-CD23 antibodies is not taught in conjunction with other well known anti-asthmatic agents such as corticosteroids and sodium cromoglycate (cromolyn).

Cockcroft et al. disclose the administration of well known anti-asthmatic agents, and disclose that administration of multiple anti-asthmatic agents offer an advantage because administration of only a single agent is often inadequate to clinically treat asthma symptoms (see entire document, particularly the abstract and discussion section). It is further disclosed that corticosteroids are desirable for combination therapy with anti-asthmatic agents since they have the advantageous property of being able to be administered prophylactically (see particularly the last sentence of the abstract and the last paragraph of the discussion on page 739).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to coadminister anti-CD23 antibodies as taught by Reff et al. and corticosteroids as taught by Cockcroft et al. because administration of any single agent may not be sufficient to control clinical asthma symptoms as taught by Cockcroft et al., with corticosteroids offering the particular advantage that they are an agent known to be effective in treating asthma that can be administered prophylactically.

Applicant has argued that the Reff et al. is not prior art based upon the declaration under 37 CFR 1.131 of inventors Michael Grunstein and Hakon Hakonarson which declares that the instant inventors conceived of the instant claimed invention prior to 2/20/1997 (the earliest claimed priority date for Reff et al.) and were diligent in constructively reducing the claimed invention to practice.



As is discussed supra, a declaration under 37 CFR 1.131 cannot be used to swear behind issued claims of a US Patent. Therefore, applicant's arguments and the declaration are insufficient to disqualify Reff et al. as prior art. The rejection is maintained.

12. Claims 1-9, 12-22, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flores-Romo et al. (Science, 1993, 261:1038-1041) in view of Mosley et al. (US Patent 5,599,905).

The office action mailed April 13, 2007 states:

Flores-Romo et al. taught that administering polyclonal antibodies that bind human CD23 (i.e. Fc $\epsilon$ R1I) inhibits the synthesis of IgE both in vivo and in vitro, and that regulation of IgE synthesis by CD23 is important in allergic diseases (see entire document, particularly the abstract). This inhibition was observed for administered whole antibody as well as administered Fab fragments (see particularly Table 1). The antibodies were present in phosphate-buffered saline and were administered via a parenteral route, specifically intraperitoneal (see note 7 and the legend of Table 1). It is further taught that administration of anti-CD23 causes a reduction in the expression of CD23 on cells (see particularly figure 3 and the first full paragraph of the left column of page 1040). These teachings differ from the instant claimed invention in that Flores-Romo et al. do not teach that asthma is an allergic disease and in that the antibodies were not administered to a human patient.

Mosley et al teach that agents which suppress production of IgE are to be used in the treatment of human diseases such as allergic rhinitis, bronchial asthma, atopic dermatitis and gastrointestinal food allergy, and that intravenous administration is a preferred route for administering such agents to humans (see entire document, particularly lines 1-43 of column 16).

As such, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to administer the anti-CD23 antibodies of Flores-Romo et al. to humans to treat asthma. Motivation to do so at the time the invention was made comes from the teachings of Mosley et al. that agents which inhibit IgE production are preferentially administered intravenously for treating asthma and the teachings of Flores-Romo et al. that administering anti-CD23 antibodies inhibits IgE production in vivo.

Note that dependent claims 6 and 19 recite that anti-Fc $\epsilon$ R1I receptor protein antibodies inhibit the binding of IgE to Fc $\epsilon$ R1I. Further, any agent that decreases a patient's total IgE level and level of cellular Fc $\epsilon$ R1I would necessarily inhibit the binding of IgE to Fc $\epsilon$ R1I since the decreased expression levels make it less likely ligand-receptor pairs can be formed.

Applicant's arguments filed January 8, 2007 have been fully considered but they are not persuasive. Applicant argues against each reference in isolation, stating that neither reference teaches all recited claim limitations.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Given that the rejection has been set forth under 35 USC 103, it is true that neither reference, in isolation, teaches every recited claim limitation.

Applicant also argues that the agents disclosed by Flores-Romo et al. and Mosley et al. do not interfere with the actual binding of IgE to Fc $\epsilon$ R1I, a limitation of the amended claims.

This argument is not persuasive because the anti-CD23 (i.e. anti-Fc $\epsilon$ R1I) polyclonal antibodies of Flores-Romo et al. were demonstrated to bind the lectin domain of CD23 which is also the domain of CD23 that is responsible for binding IgE (see particularly Figure 2 and the middle column of page 1039).

The rejection of record is maintained.

Applicant's arguments filed November 20, 2007 have been fully considered but they are not persuasive. Applicant argues that Flores-Romo et al. disclose that CD23 "could" be important in allergic diseases, and that by such wording choice on the part of Flores-Romo et al. a person of ordinary skill in the art would not be motivated to or have a reasonable expectation of success at arriving at the instant claimed invention. Applicant further argues that the agents disclosed by Mosley et al. do not comprise anti-CD23 antibodies, and that neither reference teaches administration for "the reduction of asthmatic symptoms".

This argument is not persuasive. The last sentence of the abstract of Flores-Romo et al. reads as follows: "Thus, CD23 participates in the regulation of IgE synthesis in vivo and so could be important in allergic disease." While such a statement does not guarantee success to the ordinary artisan, guaranteed success is not the standard for obviousness. Flores-Romo et al. present no data that casts doubt on CD23 participating in allergic disease, and as such it does not seem reasonable that an ordinary artisan would overlook these teachings in the absence of additional data which would question the validity of the assumptions and conclusions disclosed by Flores-Romo et al. Applicant is correct that Mosley et al. do not disclose anti-CD23 antibodies as agents which suppress IgE production. However, this does not invalidate the fact that Mosley et al. disclose that agents which suppress IgE are to be used to treat asthma, and the fact that Flores-Romo et al. present in vivo data demonstrating that anti-CD23 antibodies suppress IgE. As such a person of ordinary skill in the art would realize that anti-CD23 antibodies could be administered to a patient to treat asthma since IgE reducing agents treat asthma as disclosed by Mosley et al. and anti-CD23 antibodies are an IgE reducing agent in vivo as demonstrated by Flores-Romo et al. Note that if one treats asthma, the patient must necessarily have a "reduction in asthmatic symptoms."

The rejection is maintained.

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13. Claims 11 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Flores-Romo et al. (Science, 1993, 261:1038-1041) in view of Mosley et al. (US Patent 5,599,905) as applied to claims 1-7, 9, 12, 13, 14-20, 22, 25, and 26 above, and further in view of Cockcroft et al. (J. Allergy Clin. Immunol. 1987, 79:734-740).

The office action mailed April 13, 2007 states:

The teachings of Flores-Romo et al. in view of Mosley et al. have been discussed supra. These teachings differ from the instant claimed invention in that administration of anti-CD23 antibodies is not taught in conjunction with other well known anti-asthmatic agents such as corticosteroids and sodium cromoglycate (cromolyn).

Cockcroft et al. teach the administration of well known anti-asthmatic agents, and that administration of multiple anti-asthmatic agents offer an advantage because administration of only a single agent is often inadequate to clinically treat asthma symptoms (see entire document, particularly the abstract and discussion section). It is further taught that corticosteroids are desirable for combination therapy with anti-asthmatic agents since they have the advantageous property of being able to be administered prophylactically (see particularly the last sentence of the abstract and the last paragraph of the discussion on page 739).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to coadminister anti-CD23 antibodies as taught by Flores-Romo et al. and Mosley et al. and corticosteroids as taught by Cockcroft et al. because administration of any single agent may not be sufficient to control clinical asthma symptoms as taught by Cockcroft et al., with corticosteroids offering the particular advantage that they are an agent known to be effective in treating asthma that can be administered prophylactically.

Applicant's arguments filed January 8, 2007 have been fully considered but they are not persuasive. Applicant argues that the teachings of Cockcroft do not make up for the deficiencies of Flores-Romo et al. and Mosley et al. in teaching all recited limitations.

This argument is not persuasive for the reasons discussed supra, and therefore the rejection is maintained.

Applicant's arguments filed November 20, 2007 have been fully considered but they are not persuasive. Applicant argues that the initial rejection under 103(a) is not sustainable and that Cockcroft et al. "wholly fail to teach a combination of antibody ligands which bind CD23 with known bronchodilators for the alleviation of asthmatic symptoms."

This argument is not persuasive for the reasons discussed above. Further, if Cockcroft et al. did teach anti-CD23 antibodies in combination with other bronchodilators, the disclosure of Cockcroft would presumably be applicable as prior art under 35 USC 102(b) rather than as prior art cited as part of a rejection set forth under 35 USC 103(a).

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. The rejection of claims 1, 4-9, 11-14, 17-22, and 24-26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,630,140 has been withdrawn in view of applicant's filing of a terminal disclaimer which was accepted by the US Patent and Trademark Office on 12/13/07.

16. No claims are allowable.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL SZPERKA whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.  
Primary Examiner  
Art Unit 1644

/Michael Szperka, Ph.D./  
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